

### **REMARKS**

Claims 1-24 were pending in the application. Claim 1 is an independent claim and claims 2-24 depend therefrom. Claims 25-31 were previously withdrawn. The Applicant respectfully requests reconsideration of pending claims 1-24, in light of the following remarks.

#### **Rejections Under 35 U.S.C. §§ 102(e)/ 103(a) – Miller (Claims 1-3, 5, 9-11, 13-14 and 17-24)**

On pages 3-4 of the non-final Office Action, independent claim 1 and dependent claims 2-3, 5, 9-11, 13-14 and 17-24 were rejected under 35 U.S.C. §§ 102(e)/103(a) as being anticipated by or obvious over Miller (U.S. Patent No. 6,620,094). Without acknowledging that Miller qualifies as prior art under 35 U.S.C. § 102(e), the Applicant respectfully traverses the rejections for at least the following reasons.

With regard to the anticipation rejections, MPEP 2131 states, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed.Cir. 1987). MPEP 2131 also states, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In order for a *prima facie* case of obviousness to be established, the Manual of Patent Examining Procedure, Rev. 6, Sep. 2007 (“MPEP”) states the following:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

See the MPEP at § 2142, citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), and *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). Further, MPEP § 2143.01 states that “the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art” (citing *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007)). Additionally, if a *prima facie* case of obviousness is not established, the Applicant is under no obligation to submit evidence of nonobviousness:

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.

See MPEP at § 2142.

Regarding claim 1, the Applicant respectfully submits that Miller fails to teach, suggest, or disclose, for example, “[a] system that enhances the performance of a cochlear implant using a preprocessor, the system comprising...a first processor coupled to said at least one signal input device for performing signal processing on signal received from said at least one signal input device, wherein said first processor comprises at least one automatic-switching mechanism configured to at least one of: switch between modes of said at least one signal input device, switch between said at least one signal input device, and witch between a plurality of listening programs; and a second processor that processes and encodes the signal in cochlear implants,” as set forth in Applicant’s independent claim 1.

Miller teaches “[a]n interface system for semi-implantable and fully implantable hearing aid devices that provides direct delivery of audio input from external wireline and wireless sources to the speech processor of the hearing aid. The speech processor of the hearing aid processes the audio inputs to produce a processed signal for a transducer portion of the hearing aid that is implanted in a hearing impaired individual. In a semi-implantable hearing aid, the interface system could be included in the external portion of the hearing aid or be included in an

audio input device that replaces the external portion of the hearing aid when sound from a wireless or wireline source is desired. In a fully implantable hearing aid, an audio input device including the interface system is provided for use when sound from a wireless or wireline source is desired.” (Miller, Abstract).

With regard to “[a] system that enhances the performance of a cochlear implant using a preprocessor,” as set forth in Applicant’s independent claim 1, the Applicant notes that nowhere in Miller is there any disclosure regarding a cochlear implant. Rather, as discussed above, Miller discloses an interface system for semi-implantable and fully **implantable hearing aid devices**. As previously established in Applicant’s June 1, 2007, final Office Action response, whether the hearing aid is implanted or not, **“[a] cochlear implant is not a hearing aid.”** (“Cochlear Implantation”, Vanderbilt Medical Center, The Otology Group, [www.mc.vanderbilt.edu/root/vumc.php?site=otology&doc=5003](http://www.mc.vanderbilt.edu/root/vumc.php?site=otology&doc=5003); “Teaching Children Who Listen With a Cochlear Implant”, MED9EL Medical Electronics, Handbook for Educators, 2004, p. 40) (emphasis added). Rather, a cochlear implant is a surgically implanted electronic device that works by **directly stimulating any functioning auditory nerves inside the cochlea with electrical impulses**. The speech processor of a cochlear implant converts sound into electrical pulses that are sent to electrode contacts implanted into the cochlea. “[I]mplemented hearing aids amplify sound and transmit the sound vibrations through the ear.” (Berke, J., “Hearing Aids – Implantable, An Increasingly Viable Option,” <http://deafness.about.com/od/hearingaidbasics/a/implantableaids.htm>, Dec. 20, 2007). Thus, because Miller fails to disclose a cochlear implant, Miller cannot disclose “[a] system that enhances the performance of a cochlear implant using a preprocessor,” as recited in Applicant’s independent claim 1. Because the Office Action has failed to show “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” as required for an anticipation rejection under MPEP 2131, the rejection under 35 U.S.C. § 102(e) cannot be maintained.

With regard to “a second processor that processes and encodes the signal in cochlear implants,” as set forth in Applicant’s independent claim 1, the non-final Office Action states that

"[a] second processor in the form of a speech processor is shown at 311." (Non-Final Office Action, Page 3). However, nowhere in Miller is there any teaching of using Miller's speech processor 311 to process and encode the signal in cochlear implants. In fact, as mentioned above, nowhere in Miller is there any disclosure regarding a cochlear implant. Further, Miller only discloses one processor 311 and therefore, Miller's processor 311 cannot be a second processor. Because the Office Action has failed to show "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" as required for an anticipation rejection under MPEP 2131, the rejection under 35 U.S.C. § 102(e) cannot be maintained.

As mentioned above, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See the MPEP at § 2142, citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), and *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). The Applicant notes that the non-final Office Action fails to explicitly articulate the reasoning with some rational underpinning to support the legal conclusion of obviousness that Miller discloses "[a] system that enhances the performance of a cochlear implant using a preprocessor" and "a second processor that processes and encodes the signal in cochlear implants." In fact, nowhere in the non-final Office Action does the term "cochlear" appear. Applicants respectfully submit that this omission amounts to a failure to articulate a *prima facie* case of unpatentability and the burden to rebut this "rejection" has not yet shifted to the Applicant. Consequently, a next Office action rejecting claims 1-24 cannot properly be made final since only then would the Applicant be obligated to rebut the rejection, presuming that such an Office action sets forth a *prima facie* case. (See MPEP § 706.07(a)).

With regard to "a first processor coupled to said at least one signal input device for

performing signal processing on signal received from said at least one signal input device, wherein said first processor comprises at least one automatic-switching mechanism configured to at least one of: switch between modes of said at least one signal input device, switch between said at least one signal input device, and witch between a plurality of listening programs,” as set forth in Applicant’s independent claim 1, the non-final Office Action states the following:

Interface system 301 may contain its own circuitry and software to provide input source selection by masking out various sources and thus selecting the strongest input mode and extracting out the best signal fed into the processor. See column 6 line 50 to column 7 line 24. The examiner considers this embodiment to constitute automatic switching of sources. In addition, user selected switching may be used. Applicant provides no details as to their means for switching and thus the examiner considers such to be inherent to Miller or at least obvious.

(Non-Final Office Action, Page 3). The Applicant first notes that masking is different than switching. Nowhere in Miller is there any disclosure regarding automatic switching. Because the Office Action has failed to show “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” as required for an anticipation rejection under MPEP 2131, the rejection under 35 U.S.C. § 102(e) cannot be maintained.

With regard to the non-final Office Action’s allegation that automatic switching is inherent to Miller, the Applicant notes that a rejection based on inherency must include a statement of the rationale or evidence tending to show inherency. See Manual of Patent Examining Procedure at § 2112. “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” See *id. citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be

established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Applicants respectfully submit that neither Miller itself nor the Office Action “make[s] clear that the missing descriptive matter,” said to be inherent “is necessarily present in” Miller.

A rejection based on inherency must be based on factual or technical reasoning:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.

*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The Applicants respectfully submit that the Office Action does not contain a basis in fact and/or technical reasoning to support the rejection based on inherency. Instead, as recited above, at least claim 1 of the present application stands rejected based on a conclusory statement of inherency, rather than upon a “basis in fact and/or technical reasoning.” Accordingly, the Applicants respectfully submit that, absent a “basis in fact and/or technical reasoning” for the rejection of record, that rejection should be reconsidered and withdrawn.

With regard to the non-final Office Action’s assertion that automatic switching is at least obvious in Miller, the Applicant notes Miller teaches away from automatic switching by teaching mode selection logic included in the user interface (such as a switch) that permits a user to select a source for a desired audio sound. (Miller, Column 8, Lines 58-61). Further, as discussed above, the non-final Office Action’s conclusory statement that automatic switching is at least obvious in Miller does not establish a *prima facie* case of obviousness because the non-final Office Action fails to explicitly articulate the reasoning with some rational underpinning to support the legal conclusion of obviousness. Thus, Applicant respectfully submits that the burden to rebut this “rejection” has not yet shifted to the Applicant. Consequently, a next Office action rejecting claims 1-24 cannot properly be made final since only then would the Applicant

be obligated to rebut the rejection, presuming that such an Office action sets forth a *prima facie* case. (See MPEP § 706.07(a)).

Therefore, for at least the above stated reasons, Applicant respectfully submits that the Miller reference fails to teach, suggest, or disclose Applicant's invention as set forth in claim 1. The Applicant believes that claim 1 is allowable over Miller. Applicant respectfully submits that claim 1 is an independent claim, and that claims 2-24 depend either directly or indirectly from independent claim 1. Because claims 2-24 depend from claim 1, Applicant respectfully submits that claims 2-24 are allowable over the Miller reference, as well. The Applicant further submits that each of claims 2-24 is independently allowable. The Applicant respectfully requests, therefore, that the rejection of claims 1-3, 5, 9-11, 13-14 and 17-24 under U.S.C. §102(b) and/or §103(a), be withdrawn.

**Rejections Under 35 U.S.C. §103(a) – Miller and Griffith (Claims 4, 6-8, 12 and 15-16)**

On page 4 of the non-final Office Action, dependent claims 4, 6-8, 12 and 15-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Miller or Miller in view of Griffith et al. (U.S. Patent No. 6,842,647, hereinafter "Griffith"). The Applicant respectfully submits that claims 4, 6-8, 12 and 15-16 depend either directly or indirectly from independent claim 1. Applicant believes that claim 1 is allowable over the proposed combination of references, in that Griffith fails to overcome the deficiencies of Miller, as set forth above. Because claims 4, 6-8, 12 and 15-16 depend from independent claim 1, Applicant respectfully submits that claims 4, 6-8, 12 and 15-16 are allowable over the proposed combination of Miller in view of Griffith, as well. Applicant also asserts that each of claims 4, 6-8, 12 and 15-16 is independently allowable.

Therefore, for at least the reasons set forth above, Applicant respectfully requests that the rejections of claims 4, 6-8, 12 and 15-16 under 35 U.S.C. §103(a) be withdrawn.

**Final Matters**

The Office Action makes various statements regarding claims 1-24, 35 U.S.C. § 102(e), 35 U.S.C. § 103(a), the Miller reference, the Griffith reference, inherency, one of ordinary skill in the art, etc. that are now moot in view of the above arguments. Thus, the Applicant will not address all of such statements at the present time. However, the Applicant expressly reserves the right to challenge such statements in the future should the need arise (e.g., if such statements should become relevant by appearing in a rejection of any current or future claim).

Applicant reserves the right to argue additional reasons supporting the allowability of claims 1-24 should the need arise in the future.



Appl. No. 10/805,016  
Resp. to Office Action of May 16, 2008  
Response dated August 18, 2008

**CONCLUSION**

Applicant respectfully submits that claims 1-24 are in condition for allowance, and requests that the application be passed to issue.

Should anything remain in order to place the present application in condition for allowance, the Examiner is kindly invited to contact the undersigned at the telephone number listed below.

Please charge any required fees not paid herewith or credit any overpayment to the Deposit Account of McAndrews, Held & Malloy, Ltd., Account No. 13-0017.

Date: August 18, 2008

Respectfully submitted,

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## About.com Deafness

### Hearing Aids - Implantable

An Increasingly Viable Option

By Jamie Berke, About.com Updated: December 20, 2007

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✱ Implantable hearing aids are an option for hard of hearing people who can not use cochlear implants or hearing aids, or who may simply prefer not having any visible external parts for a hearing device. In a simplified definition, implanted hearing aids amplify sound and transmit the sound vibrations through the ear.

#### Who Can Use an Implantable Hearing Aid

At this time, implantable hearing aids are usable only by people with less than profound hearing losses.

#### Manufacturers of Implantable Hearing Aids

There are two types of "implantable" hearing aids available. One type is implanted through a surgical procedure, and the other type is implanted through non-surgical procedures.

##### Surgically Implanted Hearing Aids

Med-El, a cochlear implant manufacturer, also offers the Vibrant Soundbridge, an implantable hearing aid. Another one is the Envoy Middle Ear Implantable System (at this time, not approved for use in the United States) from St. Croix Medical (Minneapolis, Minnesota). The Bone Anchored Hearing Aid from Entific Medical Systems is a hearing aid that consists of a titanium device implanted in the bone. SoundTec also makes an implantable hearing aid that is implanted in the middle ear.

##### Non-Surgical Implanted Hearing Aids

Another is the Retrox from Auric Hearing Systems, a hearing aid that is not really implanted but consists of a titanium tube that is inserted into the ear and the hearing aid portion is inserted into the tube. Another company, Insound Medical Inc., based in Newark, California, develops hearing aids that are implanted in the ear canal through non-surgical procedures. Insound's hearing aids are worn in the canal for a period of months and removed/replaced when the batteries wear out.

##### Auditory Brainstem Implants

People who have had part of the auditory nerves removed (such as people who have Neurofibromatosis Type II) can not benefit from either cochlear implants or hearing aids. This is where the auditory brainstem implant steps in. As the name implies, it is an implant directly in the brainstem. Cochlear Corporation has developed an auditory brainstem implant. Current research information on auditory brainstem implants can be found on the National Library of Medicine's PubMed database.

#### Benefits of Implantable Hearing Aids

✱ Implantable hearing aids are still hearing aids, but implantable hearing aids are said to provide more natural, clearer sound than traditional hearing aids, because of no blockages. One apparent benefit is not having to replace batteries as frequently as with conventional hearing aids. For example, the batteries in one model have to be changed only every five years through a surgical outpatient procedure. There is no feedback to contend with. Users can control aspects such as volume with special remote controls.

**Future Growth in Implantable Hearing Aids**

The availability of implantable hearing aid choices continues to expand as more manufacturers develop them. To find out which implantable hearing aids have approval, check the [Food and Drug Administration](#) website.

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